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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|------------|---------------|----------------------|---------------------|------------------|
| 10/680,806 | 10/06/2003 | | John R. Walker | P1057US10 | 4804 |
| 29490 | 7590 | 02/10/2006 | | EXAMINER | |
| GENOMICS INSTITUTE OF THE | | | | BALLARD, KIMBERLY A | |
| NOVARTIS | RESEAR | CH FOUNDATION | | | |
| 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 | | | | ART UNIT | PAPER NUMBER |
| SAN DIEGO, CA 92121-1127 | | | | 1649 | |

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | | |
|---|---|--|--|--|--|--|--|
| Office Action Summary | 10/680,806 | WALKER ET AL. | | | | | |
| Onice Action Summary | Examiner | Art Unit | | | | | |
| The BEAULING DATE of this communication com | Kimberly A. Ballard | 1649 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period versility is provided by Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| | Responsive to communication(s) filed on 21 July 2005. | | | | | | |
| , <u></u> | | | | | | | |
| , — · · · · · · · · · · · · · · · · · · | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) ⊠ Claim(s) <u>1-89</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) <u>1-89</u> are subject to restriction and/or | wn from consideration. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11. | epted or b) objected to by the drawing(s) be held in abeyance. Setion is required if the drawing(s) is ob | e 37 CFR 1.85(a). njected to. See 37 CFR 1.121(d). | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail D | oate | | | | | |
| Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal I 6) Other: | Patent Application (PTO-152) | | | | | |

Art Unit: 1649

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-37, drawn to the first special technical feature method of inhibiting addiction-related behavior in a subject suffering from cocaine addiction, comprising administering a therapeutic agent which modulates the level of a polypeptide encoded by an elected gene.

Group II, claim(s) 38-89, drawn to the second technical feature method for identifying an agent that has the ability to prevent or inhibit cocaine addiction-related behavior, wherein the agent binds to or modulates the activity of a protein encoded by an elected gene.

Furthermore, in addition to the election of one of the above-mentioned groups, <u>for Applicant to be fully responsive</u> to the restriction requirement, <u>Applicant must elect one gene identified in Tables 1-15</u> to which the claims will be restricted.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-II appears to be that they all relate to inhibiting cocaine addiction-related behavior. However, Soyka & De Vry (*Eur Neuropsychopharmacology*, 2000, **10**: 325-332) teaches the use of an agent, flupenthixol, a neuroleptic drug with dopamine D1 and D2 receptor antagonist

Application/Control Number: 10/680,806

Art Unit: 1649

properties, as being useful in decreasing cocaine consumption. Therefore, the technical feature linking the inventions of groups I-II does not contribute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the genes listed in Tables 1-15 are known in the art and therefore do not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method of inhibiting addiction-related behavior in a subject, which is not required by the invention of Group II. Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-II and a single molecular embodiment (a gene identified in Tables 1-15) as set forth above to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-II nor the single molecular embodiment (gene) are species election requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Application/Control Number: 10/680,806 Page 4

Art Unit: 1649

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD Art Unit 1649 February 6, 2006

SUPERVISORY PATENT EXAMINER